IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
STATESVILLE DIVISION

RAMONA WINEBARGER and REX WINEBARGER,
Plaintiffs,

CASE NOS. 5:15CV57-RLV; 3:15CV211-RLV

v.
BOSTON SCIENTIFIC CORPORATION,
Defendant

MARTHA CARLSON,
Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION
Defendants

PLAINTIFFS OBJECTIONS AND COUNTER DESIGNATIONS TO DEFENDANT BOSTON SCIENTIFIC'S COUNTER DEPOSITION DESIGNATIONS OF JAMES GODDARD TAKEN MARCH 28/29, 2013

BSC Counter Designation	Objection	Plaintiffs Counter Designation to BSC Counter Designation
jg032813, (Pages 185:19 to 188:4) **185** **19 Q. That Boston Scientific feels like** **20 the current specifications and design is adequate** **21 to control this failure mode and the effect from** **22 it, right?** **23 MR. ANIELAK: Object to the form.** **24 A. It's put in there to control the** **186** **1 design feature. So we're utilizing the product** **2 spec. It indicates the mesh design feature such** **3 as pore size, and that's what's being controlled**		

here. Q. Okay. And then as far as the recommended actions to control poor tissue ingrowth which causes a failure of erosion, exposure, dehiscence and necrosis is what, what do they recommend as far as any recommended actions. None, right? A. No, the company believed that we had enough knowledge at this point based upon mesh design, previous use of mesh, published literature that this product specification characterizing the pore size was an adequate control. Q. Again, my question is, their recommended action for this failure mode was none, correct? A. Yes, it was none based upon the knowledge base that we had at the time. Q. Boston Scientific had the ability to develop lighter weight mesh or develop larger pore size mesh and market that themselves if they 187 had wanted to prior to this, didn't they? MR. ANIELAK: Object to form. A. They had a knowledge base to -- Q. I'm sorry. A. -- to go with a wide, a very broad design. Q. Right. A. And the mesh design that we initially chose to proceed with was Polyform. And if you look at the design of Polyform at the time that it was commercialized, it was a large pore knit mesh, it was a lightweight mesh relative to other products that were on the market, so it fit the criteria against published literature around these types of mesh implants and what has done well, what was safe and effective.	186:22-187:22 FRE 403, Cumulative	

18 Q. It was the heaviest mesh as opposed 19 to others on the market, wasn't it? 20 A. No. 21 Q. It wasn't? 22 A. No. 23 Q. It was one of the heaviest ones 24 that was being used in prolapse kits at the time, 188 1 wasn't it? 2 A. No. 3 Q. Are you sure about that? 4 A. Yes.		
jg032913, (Pages 481:3 to 485:4) 481 3 Q. Good afternoon, Jim. Why don't you 4 tell the jury a little bit about yourself? 5 A. I am married living in 6 Massachusetts here. I have two daughters and a 7 grandchild at this point. I've been living in 8 Massachusetts for about 20 years it's been. 9 Q. And describe your educational 10 background? 11 A. My educational background. I have 12 an engineering degree, specifically in plastics 13 engineering, that I completed in 1984. 14 Q. And the plaintiffs previously 15 marked as Deposition Exhibit No. 43 a copy of a 16 description of your work experience; is that 17 right? 18 A. Yes. 19 Q. Describe a little bit about what 20 your employment history is, where you've worked 21 and what positions you've held? 22 A. This document contains a work 23 history that spans from 1987 to present, and that 24 basically covers the time that I've spent within 482 1 the medical device industry. So I started with 2 CR Bard back in 1987, worked on various feeding 3 products as well as angioplasty balloons, stayed	BSC has previously designated the same testimony. Plaintiffs adopt and incorporate any objections as set forth in their counter-designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.

there for about six years, and then moved on to Vision Sciences which is a company that developed proprietary endoscope devices. In that regard, I worked on the disposable device that was associated with that proprietary technology. From there -- after spending about five or six years there, I went on to Eligix in which I was involved or managed the development of the disposables component used for that cancer therapy process, and subsequently moved on to Boston Scientific in 2003.

Q. And I'm going to jump in there. When you started at Boston Scientific in 2003, what division did you come into, where did you start working?

A. I worked at the urology women's health division in Boston Scientific.

Q. And what products are covered by that division, what types of research and development goes on in that division?

A. There are basically for that

division two key types of products, pelvic floor repair type products, midurethral slings as well as pelvic organ prolapse and, also, the gynecology type product which is the system that treats abnormal uterine bleeding.

Q. And when you started at Boston Scientific in 2003, what position were you hired into?

A. I was hired as a senior R & D engineer.

Q. And is that still your current position?

A. No.

Q. And what position do you have today?

A. Currently I'm an R & D manager and have held that since 2005. In --

Q. Go ahead. **A. In that role I'm the functional manager for R & D engineers that work on products, specifically for the pelvic floor franchise.** **Q. So describe what the difference is between when you were the senior R & D engineer** **484** **in 2003 to 2005 to when you became a manager in 2005. Functionally how did your responsibilities change?** **A. Okay. As a senior R & D engineer, someone in that role would be definitely having more of a hands-on involvement with the design and development of the product, so they would be generating and evaluating prototypes, completing some of the testing or directing the completion of testing, generating documentation and that sort of thing within that product development cycle.** **As a functional manager, again, I manage the engineers that are associated with those tasks, so I will not be so hands-on but provide guidance around those activities and basically prioritize some of their activities as well.** **Q. And when did your role change from being the more hands-on engineer on projects to being more in a management role, when did that transition occur?** **A. About the same time that I received that title which was 2005.** **485** **Q. How many -- approximately how many**		

2 engineers do you manage in your research and 3 development group? 4 A. Currently six.		
jg032913, (Pages 487:16 to 488:7) 487 16 Q. When Boston Scientific puts a team 17 together to develop a new product, why does it 18 involve -- why does it get a cross-functional 19 team in place, what is the purpose of that? 20 A. Well, the R & D group does not 21 possess all the knowledge and the skills to be 22 able to develop these products, so we really need 23 to be able to utilize that type of knowledge and 24 information and have that type of input to bring 488 1 these products to market. 2 Q. And when you say these products, 3 would that -- cross-functional teams, would they 4 be put in place for the R & D efforts 5 consistently across product development in your 6 experience? 7 A. Yes.	BSC has previously designated the same testimony. Plaintiffs adopt and incorporate any objections as set forth in their counter-designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.
jg032913, (Pages 488:13 to 495:2) 488 13 Q. I want to talk about POP or pelvic 14 organ prolapse. In general, what is your 15 understanding of that condition? 16 A. That's a condition where through 17 childbirth and other potential causes there is 18 some connective tissue that is no longer holding 19 the pelvic organs in place satisfactorily, and 20 the devices that we have developed provide the 21 physician with an option for treating that type 22 of condition? 23 Q. And at Boston Scientific what 24 devices have you been involved with the research 489 1 and development efforts of that have ultimately 2 become commercialized?	BSC has previously designated the same testimony. Plaintiffs adopt and incorporate any objections as set forth in their counter-designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.

A. That would include the Pinnacle and Uphold devices. Q. I want to talk generally about the process of research and development of a new product like the slings or the treatments, the devices for pelvic organ prolapse. In general what are the steps to bring a product through the research and development process? A. There's a very thorough process, and at a high level we collect input to help design or define what that design should be, then verify that design and ultimately validate, and in collecting that input per se, we're working closely with physicians, and specifically with Solyx and the Pinnacle and Uphold, these were products that were brought in to BSC as far as an idea, a design that these physicians had in mind. So Dr. Mamo brought to us that Solyx idea. The Uphold product was something that Dr. Goldberg had developed on his own, in looking at a way to create a mesh shape that would work best for a hysteropexy procedure, and Dr. Miller brought 490 forth an idea around the placement of the arms of the mesh profile in the sacrospinous ligament. So in those products or programs, we worked closely with those physicians to further develop that idea, and we also brought in multiple other physicians to also take a look at how we were approaching this, just to confirm that we were hearing from these one or -- you		

know, one physician that brought the idea that that makes sense, and the way we proceed with that is through bioskills labs, which are working with cadavers basically, and our frequency in doing that would happen almost once a month or so to iterate that process. So a lot of that information goes into the input documents, if you will. We create a market specification, a product specification. We start our risk management aspects of it. So we look at if we're moving toward this design what potential failures could occur. So we start assessing that early on to make sure that we put the controls in place to minimize the risk associated with that.

Q. You described one of the initial stages of product development for the slings that

we talked about or the pelvic floor prolapse repair kits is the inputs or specification stage. What is that? What happens at that particular stage of R & D?

A. That's where we're taking the voice of the customer information which ends up in our -- we create a market specification around that. So that's listening to customers to understand what kind of features they're looking for in a kit such as this. From an R & D perspective we then take that more generalized terms that are inserted into a market spec and translate them to more engineering terms, so dimensions or strengths and things like that or specifically calling out the biocompatibility testing that needs to be done.

Q. You mentioned certain doctors like Dr. Mamo or Dr. Miller or Dr. Goldberg with respect to Solyx, Pinnacle and Uphold respectively. Are there other doctors that were involved with those products at the specification, at the very early stages about what the designs of the products might look like? A. Yes, absolutely. So we -- as I 492 mentioned, we begin the bioskills lab very early on. At that point we're bringing in multiple physicians to give us feedback. Q. What is the next stage? After you've obtained feedback and gathered information from doctors about what the product specifications might look like, what's the next phase of research and development at Boston Scientific? A. Basically at that point we're looking to take that input document and derive a design, a finalized design on that, and we call that phase basically freezing the design. We do some initial testing and show that, yes, we have pretty good confidence that we'll meet the product spec requirements that we put in place. Subsequent to that we're into the verification phase of the design, so we build product and we do the testing, the biocompatibility testing, the general performance testing, which could be tensile testing to see how strong things are, the flexibility, those types of mechanical testings to characterize and make sure that, again, we're building a product that meets the specifications 493		

that were generated based upon physician input. So it's a connective process to make sure that all that information is brought through. And then once we get through the verification process, we go back to the basically upfront again, and we say, okay, we've built this product, and we're putting it back in the hands of physicians, and we're asking them to come in, work with us, again in the similar-to-use environment, the cadavers, to take this product that we're pretty close to getting ready to commercialize. We've completed all our verification testing, we have our designs completed, please give us the final feedback that you can confirm that we're hitting the mark here. Q. And the bioskills labs are -- who would attend those, who generally goes to those bioskills lab? A. It is the people that are on the project team will be working closely with the physician, so there's typically a number of physicians that come and place the mesh product. Q. And in terms of getting medical and clinical feedback, how does that happen at these		
494 stages of research and development, how are you collecting their input? A. Their input? Through just discussions and questions around the procedure and the cadaver labs, but we're also putting in front of them what we propose for directions for use. So we're asking them about the procedure. This is what we see as the potential		

10 effects and complications. This is what we're 11 seeing based upon your initial input on the 12 procedure steps. Does this make sense, are we 13 capturing everything, just to be sure that we're 14 having -- putting forth all the information 15 needed in that DFU. 16 Q. And what is the final stage of R & 17 D to bring a product like Uphold or Pinnacle to 18 market, what's the final stage? 19 A. The final stage is to ensure that 20 all the processing, the manufacturing, that shows 21 capability; the design validation is in place; 22 and then basically, again, we do a very thorough 23 paperwork exercise of documenting all of this, 24 and we need to make sure that that is there, the 495 1 regulatory clearance is in place for whatever 2 region of the world we're distributing it.		
jg032913, (Pages 496:18 to 502:16) 496 18 Q. I want to talk a little bit about 19 Pinnacle now. You mentioned that Dr. Miller was 20 originally involved with the idea behind the 21 Pinnacle product. Describe for me who Dr. Miller 22 is and how he was involved initially? 23 A. Dr. Miller is a urogynecologist out 24 of -- practicing in Wisconsin, and again, he came 497 1 to Boston Scientific with an idea in mind about a 2 way to basically fixate the mesh in the anatomy. 3 The sacrospinous ligament was something that was 4 already being used as an anchoring point, a 5 suturing point for these types of products. The 6 tie-down suture potentially is not necessarily 7 the best. It could lead to pain and such. So he	496:18- 502:16 FRE 403	

had an idea of why not bring the mesh through the sacrospinous ligament as a fixation point, and he was well aware of our Capio device and saw that the two could work together to create a differentiated product, in the sense that to move away from the trocar based, again multiple incision-based products, such as Prolift and Apogee, Perigee and Bard's Avaulta which were out in the market.

Q. So describe for me that in a little bit more detail. What was the idea behind Pinnacle as opposed to the trocar-based systems that were on the market?

A. With the Pinnacle device -- I should back up and say with the trocar-based products that were out on the market, the physician is not only making an incision

vaginally but also having to come from skin incisions elsewhere on the body to come in around and basically place this mesh product with the -- and these are blind trocar passages. With the Capio device, the physician is only making a single incision in the vaginal wall, whether it be the anterior side or the posterior, and completing his dissection and using the Capio to get to those fixating points without the use of the blind trocar passages.

Q. You mentioned that there were two products that were being brought together to form Pinnacle. What do you mean when you say there was two products that were being brought together?

A. As I mentioned, the Capio device was something that these types of physicians, urogynecologists, gynecologists and urologists,

were already using for their pelvic surgery, and prior to the development of the Pinnacle and Uphold products, the Polyform mesh sold in the sheet form had already been commercialized and had been on the market for a little while. So we basically took those two technologies to be able 499 to provide something that would be utilized in the Capio and provide a single incision approach along with a precut mesh shape? Q. So the Polyform mesh that was being used, ultimately that was used in Pinnacle and Uphold, was already on the market and being commercialized at the research and development stage for Pinnacle and Uphold? A. Yes. Q. Did Dr. Miller remain involved through the R & D process with Boston Scientific? A. Yes, he did. Q. And were there other doctors besides Dr. Miller that were also involved in the research and development efforts of the Pinnacle device? A. Yes, yes. Q. And how would those doctors be involved? How would Boston Scientific obtain their feedback and their input? A. They were brought in. As we produced prototypes to look at different ideas and features, we brought physicians in to use them in the cadaver scenario. So we were looking 500		

to find out what would be the best approach of delivering this product in the mesh, so the physicians provided us feedback as to, you know, is it passing through the ligament correctly. Once it's placed, do they see that it's placed correctly, it's laying correctly. Those types of things. Is the shape generally where they would expect or want to see it.

Q. How often do you have those types of bioskills labs, those cadaver labs during the development process? How frequently are you having those?

A. When we're heavily focussed on that part of it, during that, it's probably about once a month, so that gives us the chance to, you know, have that time with the physicians, get that feedback and then iterate. So we have a few weeks to iterate, make some new prototypes, get some physicians back in again, a new look at the changes that we're making.

Q. When you use the term iterate, what does that mean?

A. So basically we would adjust the design based upon the feedback from the

physicians.

Q. So you may have a bioskills lab where doctors would come in and use a prototype, and based on their feedback, you may make changes or iterate to the next version?

A. Yes.

Q. For Pinnacle to get through the input stage, the verification stage, ultimately get validated and all of the testing and biocompatibility testing that you mentioned, as

well as all the bioskills lab and the doctor feedback and the host of other requirements, how long does that take to get through that R & D process generally, or in Pinnacle how long did it take? A. About two and a half, three years. Q. And why does it take that long? Why does it take two and a half to three years to get a pelvic floor product from the idea stage on to the market? A. There are basically a lot of knowledge gaps to be filled. So we get some information upfront, we assess it, you know, is this something that we're capable of doing, does 502 it make sense, is it going to offer the patient with some value, and then we -- there's just a lot of information that we need to collect to show that this design is going to be the correct design, and based upon that physician input, be what they are looking for. So we -- again, going through those steps is just time-consuming to get there. The testing is not short per se. We also do shelf-life testing which has a certain time period to get completed, so it's not something that can be turned around in a month or two. Q. All of that work with doctors and the testing and the shelf-life testing, all that is being done to come up with a safe and effective device? A. Correct. Absolutely, yes.		
jg032913, (Pages 502:17 to 507:1) 502 Q. I want to talk about Uphold now. You mentioned Dr. Goldberg was involved with the	BSC has previously designated the same testimony. Plaintiffs	Plaintiffs adopt and incorporate their counter designations, if any.

19 Uphold device. Who is Dr. Goldberg and how was **20 he involved with that device?** **21 A. Dr. Goldberg is a urogynecologist** **22 out of Chicago, and he had been using our** **23 Repliform product in developing a hysteropexy** **24 procedure and subsequently did some procedures** **503** **1 with Polyform as well, and he basically came to** **2 Boston Scientific with this proposed mesh shape** **3 using either Repliform or Polyform as a potential** **4 kit where a physician could achieve apical** **5 support, basically holding up those organs, but** **6 also for uterine preservation where a** **7 hysterectomy may not need to be done.** **8 Q. So what was the need that** **9 Dr. Goldberg was trying to satisfy with his idea** **10 on Uphold?** **11 A. He was looking to be able to do the** **12 repair but maintain the uterus in position.** **13 Q. And what advantages did Uphold have** **14 based to -- strike that.** **15 What advantages did Uphold have** **16 compared to the trocar-based systems that were on** **17 the market prior to that?** **18 A. The Uphold product also utilized** **19 the Capio device. So the single incision** **20 approach was able to be achieved, no blind trocar** **21 passage, plus the Uphold basically had mesh only** **22 where it was needed, so it was a smaller mesh** **23 footprint or amount of mesh that's implanted.** **24 Q. Why did Boston Scientific pursue** **504** **1 both Pinnacle and Uphold? What was the reasoning** **2 behind having two different options available?** **3 A. The Uphold, again, allows a**	**adopt and incorporate any objections as set forth in their counter-designations, if any.**	

physician to really minimize the amount of mesh. The anterior apical is a broader area of mesh to be able to support some defects in the other areas where the Uphold may not cover. Q. Was Dr. -- strike that. Was Dr. Goldberg involved with the R & D efforts after he came to the company with the idea? A. Yes. Q. How so? A. He was involved with bioskills labs as we progressed through that design iteration. Q. And were other doctors besides Dr. Goldberg brought into the research and development process to give their input and feedback as well? A. Yes. Q. And how did that happen? A. That was -- typically in these bioskills labs we would have more than one physician come, so there would be multiple physicians potentially that would take a look at 505 the design, provide us with their feedback, and we would iterate based upon that. Again, our desire to have multiple physicians was to verify this direction that Dr. Goldberg suggested we go off in and to make sense it's going to be a solid option for them to use in this procedure. Q. How long did the R & D efforts take for Uphold from around the time when Dr. Goldberg came to the company with the idea until ultimately it reached the market? A. About three years. Q. You mentioned that there were other devices on the market to treat pelvic organ prolapse, mesh products, prior to the commercialization of Pinnacle and Uphold. How did those other products on the market impact		

18 Boston Scientific's development into Pinnacle and 19 Uphold? 20 A. We evaluate that in a number of 21 areas. We purchase those products from an R & D 22 perspective and get an understanding of the 23 design features associated with that, so the 24 dimensions on the delivery devices, the mesh 506 1 configuration, the mesh material, the mesh shape. 2 We also look at, as a team, look at the published 3 literature that's been out -- that's out there on 4 these previously marketed devices. The MAUDE 5 database type of information is also collected by 6 team members to look at what type of feedback may 7 be collected there. 8 Q. I want to talk a little bit about 9 biocompatibility. What does biocompatibility 10 mean, what is your understanding of that? 11 A. My understanding of 12 biocompatibility is really a test or an 13 assessment of how a material affects tissue. 14 Q. And did Boston Scientific evaluate 15 the biocompatibility of the mesh contained in its 16 Pinnacle and Uphold devices? 17 A. Yes, there are industry standards 18 that are widely recognized that lay out specific 19 tests to be completed based upon how a device is 20 being used. 21 Q. And did Boston Scientific conduct 22 tests to determine biocompatibility of its mesh 23 used in Pinnacle and Uphold? 24 A. Yes, there's multiple tests that 507 1 are done.		
jg032913, (Page 507:4 to 507:9) 507 4 What did Boston Scientific	BSC has previously designated the same	Plaintiffs adopt and incorporate their counter designations, if any.

5 ultimately conclude about the biocompatibility of 6 the mesh used in the Uphold and Pinnacle devices? 7 A. These materials were found to be 8 biocompatibility based upon the test acceptance 9 criteria.	testimony. Plaintiffs adopt and incorporate any objections as set forth in their counter-designations, if any.	
jg032913, (Pages 507:11 to 508:8) 507 11 What is the material that's used 12 for the mesh that's in Pinnacle and Uphold? 13 A. Polypropylene. 14 Q. Do you believe that's an 15 appropriate choice for Boston Scientific's mesh 16 devices? 17 A. Yes. 18 Q. Why, why do you believe that's an 19 appropriate material? 20 A. It is a material that has a long 21 history of use not only in many medical devices 22 but also for implanted products or implanted 23 materials. So it's been in the hernia market. 24 There are polypropylene sutures that have been 508 1 around a number of years as well. And then the 2 predicate vaginal meshes were of polypropylene 3 for the most part. So we decided that there's a 4 body of evidence to suggest that that would be an 5 appropriate material. We did our own testing to 6 basically confirm that aspect, and that's, you 7 know, what supports its use for safety and 8 efficacy.	BSC has previously designated the same testimony. Plaintiffs adopt and incorporate any objections as set forth in their counter-designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.
jg032913, (Pages 512:12 to 513:15) 512 12 (Exhibit No. 70 was marked 13 for identification.) 14 Q. (By Mr. Anielak) I've marked as		

15 Deposition Exhibit No. 70 a meeting request; is 16 that right? 17 A. Yes. 18 Q. And if you look at what we call the 19 Bates numbers down in the bottom corner -- 20 A. Mm-hmm. 21 Q. -- you can see that the Bates 22 number for the meeting request ends in 8803. Do 23 you see that? 24 A. Yes. 513 1 Q. And Exhibit No. 51, the agenda, is 2 basically the next Bates number in that order, 3 right -- 4 A. Yes. 5 Q. -- 804. And according to the 6 meeting request that is the document right before 7 the agenda, when did the meeting occur that the 8 agenda is a reference to? 9 A. This indicates here the start was 10 on April 6, 2010. 11 Q. So the agenda did not relate to any 12 type of meeting that occurred in 2008 as 13 represented by the plaintiffs' lawyer did it? 14 MR. MOODY: Objection to form. 15 A. That's correct.	513:11-15 Foundation, FRE 403	
jg032913, (Pages 518:12 to 523:16) 518 12 Q. (By Mr. Anielak) Exhibits 52 and 53 13 reflect some discussions that Boston Scientific 14 had with Proxy in November of 2008. Do you 15 remember that discussion from yesterday? 16 A. I do. 17 Q. At the time that Boston Scientific 18 was having these discussions with Proxy, were 19 Pinnacle and Uphold on the market? 20 A. Yes, they were. 21 Q. In terms of the development of the 22 Lite mesh, that timeline, where were these 23 discussions on that timeline of the research and 24 development into Lite mesh? 519		

A. These were discussing prototypes, so early samples that Proxy was supplying to us to get some feedback on our thoughts on that particular design. So these were initial samples which were then modified to change properties here and there based upon some feedback we provided them, so it's very beginning. We were just starting the process of looking at this alternate, and then it wouldn't -- it followed up with a full scale program to incorporate this mesh material into our pelvic floor repair kit.

So as I described earlier, this product would go through the same sequence of events in collecting information from physicians, taking these prototypes, putting them in their hands, getting feedback on, you know, is this performing the same way or as you would expect it to, developing the design specifications, going through the verification process of testing it through biocompatibility, through other performance criteria, functional testing. We completed a regulatory submission for this product. We needed to go through the validation which, again, bringing physicians in to take a

look at that final design and confirm that this is what they would -- that they gave us a final blessing that it was the product that they would expect to see.

Q. Did Boston Scientific commercialize and market the Lite product that was discussed in these documents in 2008?

A. Not domestically, no.

Q. Okay. Did Boston Scientific --

A. Not international either. I'm

sorry. Q. That's all right. Did Boston Scientific market in the United States the Lite product in 2009? A. No. Q. Did Boston Scientific market the Lite product in 2010? A. No. Q. Did Boston Scientific market the Lite product in 2011? A. Not domestically, no. Q. And when ultimately in the U.S. did Boston Scientific market the Lite product? A. January 2012. There was some 521 manufacturing issues that were realized that we needed to look at more closely concerning the tack weld. Going to the difference in mesh, that was another area that we needed to look at more closely. Q. Was Boston Scientific in a position to commercialize and market the light weight mesh in the United States in 2008? A. No. Q. Was Boston Scientific in a position to commercialize and market the light weight mesh product in 2009? A. No. Q. Was Boston Scientific in a position to commercialize and go to market with the light weight product in the United States in 2010? A. No. Q. Was Boston Scientific in a position in 2011 to market and commercialize the light weight product? A. No. Q. When did that ultimately happen? A. It ultimately received FDA clearance the latter part of 2011, and the 522 initial launch domestically was completed in early 2012.	521:22-522:2 FRE 401, 402, 403 FDA	

Q. You mentioned the manufacturing issues that the light weight mesh presented. What were those? A. Basically the differences in mesh. You've got less surface area with the lighter mesh than there is with the standard mesh, so that affected the tack weld or the capability of producing a tack weld within our specifications. So we were able to achieve a design that was capable for Uphold but more difficult with the other designs. Ultimately we incorporated the design change of removing the tack weld and using the polypropylene loop alone for securing the two together. Q. How long did that process just to solve the manufacturing problems, how long did that take? A. About six months or so. Q. In 2008 when you were meeting with Proxy, did you know whether you could even manufacture the light weight mesh products into Uphold, did you know that when you were sitting	522:2-522:2-FRE 401, 402, 403 522:21-523:12 FRE 401, 402, 403	

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with them in 2008?
A. No, we didn't have that depth of knowledge from back in 2008, and I may have commented earlier that we had the so-called capability, and my perspective on that was at a high level. The knitting process was there, and we expected the processes that we had in place for standard to be -- the standard mesh product to be very similar, so that from that perspective

10 we had our eyes on the general capability, but 11 there was still a lot to be learned around design 12 and verification and validation thereof. 13 Q. If you could look at Exhibit 55. 14 And yesterday the plaintiffs' lawyers asked you 15 about the slide that ends in Bates No. 692. 16 A. Yes.		
jg032913, (Page 524:10 to 524:23) 524 10 Q. Does that mesh have a low weight, 11 is that a low weight mesh? 12 A. It has low weight, yes, relative to 13 other meshes that were on the market when that 14 was launched, yes. 15 Q. Does it have a low surface area, 16 that mesh? 17 A. Low surface area again relative to 18 other meshes that were on the market at the time 19 it was launched. 20 Q. And does that mesh used in the 21 Pinnacle and Uphold devices, is it large pore 22 size? 23 A. Yes.	524:10-23 FRE 403	
jg032913, (Page 525:2 to 525:22) 525 2 Q. I want to talk a little bit about 3 weight. At the time that Boston Scientific began 4 marketing Pinnacle and Uphold back in 2008, was 5 the mesh that was used in those devices, was that 6 the heaviest mesh that was in a device to treat 7 pelvic organ prolapse? 8 A. No, no. The Ethicon or J&J 9 product, the Prolift, incorporated the Gynemesh 10 which has a heavier weight that's around 50 grams 11 per square meter versus the Polyform mesh that 12 was at 40. 13 Q. Would you characterize the mesh 14 that's used in the Pinnacle and Uphold devices as	525:13-22	

a heavy mesh? A. No. Q. Why not? A. No, because the -- that term is difficult to use in this because there's always that changing target, but relative to where mesh have changed over the years, we're definitely in that realm of a light weight mesh.	FRE 401, 402, 403, 701, 702	
jg032913, (Pages 526:5 to 527:16) 526 Q. And there's a chart that reflects the pore size on the Polyform mesh. Do you see that? A. Yes. Q. And the Polyform mesh is what's being designated there as the mesh that's in the Uphold and Pinnacle devices? A. Yes. Q. And it indicates there's a pore size of 1400. Do you see that? A. I do. Q. Is that a large pore size or a small pore size? A. That is considered a large pore, and I reference that back to a publication by a Dr. Amid talking about mesh characteristics where he was looking at mesh design, whether it has monofilament or multifilament and pore size, and this -- he was basing that upon what he had seen and studied with meshes and how they react, and 527 he characterized the larger pore as being greater than 75 microns. Q. We saw a reference to pore size in the FMEA that the plaintiffs' lawyers asked you questions about yesterday. Was pore size considered at the research and development stage? A. Yes, we have a pore size of greater	BSC has previously designated the same testimony. Plaintiffs adopt and incorporate any objections as set forth in their counter-designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.

than 500 microns indicated in our product specification. **Q. And why did you set a pore size of greater than 500 microns as part of the product specification?** **A. It was based partly upon what we had read in the literature and looking to achieve the desired mesh properties overall, so maintain the strength but also a large pore configuration.**		
jg032913, (Pages 529:15 to 530:12) **529** **Q. She left out the e.g. Can you just read what the e.g. there says in parentheses?** **A. "Graft shrinkage associated with tissue incorporation and pore expansion."** **Q. And in terms of the comment about graft shrinkage in this paragraph of the patent and the other part of the patent, what are you referring to? When you say graft shrinkage in this context, what are you referring to?** **A. The graft shrinkage and my thoughts** **530** **around that was it's not the polypropylene material or the fiber that's changing its configuration. It's the tissues effect on that, the overall knit structure, that's causing some shapes to be changed.** **Q. And is that consistent with what you've stated in the patent?** **A. Yes.** **Q. And is that consistent with what you've told the ladies and gentlemen of the jury during your deposition over the last two days?** **A. Yes.**		***jg032913, (Page 395:16 to 395:23)*** ***395*** ***Q. (By Ms. Copeland) Mr. Goddard, you have had an opportunity now to review Exhibit No. 61, right?*** ***A. Yes.*** ***Q. And this is some literature. It's a study by Dr. Donald Ostergard, correct?*** ***MR. ANIELAK: Object to the form.*** ***A. It's a summary of information.*** ***jg032913, (Pages 398:23 to 399:3)*** ***398*** ***Let me go back to the left-hand side, the bottom. It says, "In 1998 Klinge*** ***399*** ***reported shrinkage of 30 percent to 50 percent after four weeks." Do you see that?*** ***A. Yes.*** ***jg032913, (Page 399:8 to 399:21)*** ***399*** ***Do you believe that there's shrinkage associated at 30 percent to 50 percent***

		after four weeks of implantation of pelvic mesh devices? *MR. ANIELAK: Object to the form.* *A. The tissue is what's shrinking.* *It's not the mesh that's shrinking, and I don't -- from this statement we don't know what product he's talking about, so there's not much information there.* *Q. You said something interesting. It is your testimony that the mesh doesn't shrink, that's your testimony?* *A. Yes, it's the tissue that shrinks* *jg032913, (Pages 547:20 to 550:5)* *547* *Q. And in that paragraph I've highlighted what you read. It says -- the last sentence, the last part of the sentence it says, "e.g. graft shrinkage associated with tissue incorporation and pore expansion." Do you* *548* *remember that?* *A. Yes.* *Q. And the point of them having you read that was so you could try to establish that the mesh itself doesn't shrink. That's your point, that's what you think, right?* *MR. ANIELAK: Form.* *A. The polypropylene material itself,*

		like the strands, are not reducing in length at all, no. *Q. And that's what you believe, correct?* *A. Yes.* *Q. All right. But what happens is is the product itself and the inflammatory response caused by your product causes the shrinkage, right, that's what you believe?* *A. The tissue reaction, the way the tissue forms around the mesh can lead to that, yes.* *Q. It can lead to a shrinkage of somewhere between 30 to 50 percent. Do you believe that?* *MR. ANIELAK: Form.* *549* *A. I know that there are shrinkage rates out there. I'm not that well acquainted with them.* *Q. Well, you've seen the literature that was on the board this morning from the medical literature I think that you saw. Do you recall that?* *A. I've seen a lot of different data. I don't exactly know the numbers but.* *Q. I will get it back out for you, but the data said 30 to 50 percent shrinkage, I believe. Do you recall that?*

		13 MR. ANIELAK: Form. *14 A. It may be. I would have to look at* *15 it again.* *16 Q. Do you think that that presents a* *17 problem for the women who this is implanted in?* *18 A. I would ask you to speak to the* *19 medical people more specifically about that. For* *20 a physician to categorize if that is a problem* *21 what level of shrinking would be a problem versus* *22 not.* *23 Q. Does Boston Scientific care about* *24 that?* *550* *1 MR. ANIELAK: Form.* *2 A. We have -- we recognize that as a* *3 potential complication and include that in our* *4 instructions for use for the device, so they* *5 recognize that as an outcome potentially.*
jg032913, (Pages 530:13 to 531:12) **530** **13 Q. In general when you're involved** **14 with designing and developing products like** **15 Pinnacle or Uphold, what is the focus, what are** **16 you trying to achieve when you're involved in** **17 that process?** **18 A. We are listening to the customer,** **19 so we're basically getting feedback or input from** **20 physicians on device design, and we are looking** **21 to incorporate what they see as user interface** **22 values in their patient safety aspects into these**		

23 designs, and that's evident in the Pinnacle and **24 Uphold design where we moved away from this blind** **531** **1 trocar passage to the single incision Capio. So** **2 we're offering the customer an option to a** **3 surgical procedure looking to incorporate their** **4 input into that.** **5 Q. Do you believe that Boston** **6 Scientific's devices, the medical devices that** **7 you've been involved with like Pinnacle and** **8 Uphold and Solyx, are safe?** **9 A. I do.** **10 Q. Do you believe that those products** **11 are effective options for doctors?** **12 A. I do.**	**531:5-12** **FRE 401, 402, 403, 701, 702**	

1. **Counter Exhibits to Counter Exhibits**
   a. Goddard 61
   b. Plaintiffs adopt and incorporate the exhibits designated in their counter designations for this witness.

DATED: July 20, 2015

Respectfully Submitted,

TRACEY & FOX LAW FIRM

/s/ Sean Tracey
Sean Patrick Tracey
State Bar No. 20176500
Shawn P. Fox
State Bar No. 24040926
Clint Casperson
State Bar No. 24075561
440 Louisiana, Suite 1901
Houston, TX 77002
(800) 925-7216
(866) 709-2333
stracey@traceylawfirm.com
sfox@traceylawfirm.com
ccasperson@traceylawfirm.com

/s/ *John R. Fabry*

John R. Fabry
Texas Bar No. 06768480
Mark R. Mueller
Texas Bar No. 14623500
MUELLER LAW, PLLC
404 West 7th Street
Austin, TX 78701
(512) 478-1236
(512) 478-1473 (Facsimile)
John.Fabry@muellerlaw.com
Mark@muellerlaw.com
Meshservice@muellerlaw.com

CERTIFICATE OF SERVICE

I hereby certify that on July 20, 2015, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

TRACEY & FOX LAW FIRM

/s/ Sean Tracey
Sean Patrick Tracey
State Bar No. 2176500
Shawn P. Fox
Clint Casperson
State Bar No. 24075561
State Bar No. 24040926
440 Louisiana, Suite 1901
Houston, TX 77002
(800) 925-7216
(866) 709-2333
stracey@traceylawfirm.com
sfox@traceylawfirm.com
ccasperson@traceylawfirm.com

/s/ *John R. Fabry*
John R. Fabry
Texas Bar No. 06768480
Mark R. Mueller
Texas Bar No. 14623500
MUELLER LAW, PLLC
404 West 7th Street
Austin, TX 78701
(512) 478-1236
(512) 478-1473 (Facsimile)
John.Fabry@muellerlaw.com
Mark@muellerlaw.com
Meshservice@muellerlaw.com